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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,519	09/18/2000	Michael C. Barney	660005.98757	4670

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.** 09/664,519	**Applicant(s)** BARNEY ET AL.	
	Examiner Chih-Min Kam	**Art Unit** 1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *8 and 22*.

   Claim(s) rejected: *1-7,12-21 and 23-25*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____

10. ☒ Other: *Change of correspondence address has been entered.*

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 103(a). In the amendment of September 29, 2003, claims 2, 13, 16 and 24 have been cancelled, and claims 1, 12, 15 and 23 have been amended. Applicants' response has been fully considered, however, claims 1, 3-7, 12, 14, 15, 17-21, 23 and 25 are rejected under 35 USC 103(a).

If applicants' amendment were entered, it would have the following response:

1. Claims 1, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutter et al. (WO 98/11883) in view of Todd et al. (U. S. Patent 5,082,975). Nutter et al. teach a method of killing cancer cells or bacterial cells, and/or inhibiting their growth through the use of beta acids such as hexahydrocolupulone (HHC) and a pharmaceutical composition comprising the beta acid and a pharmaceutical carrier, which can be used as a topical ointment for topical administration to inhibit the growth of Staphylococcus aureus. The reference indicates lupulones can be administered in a dosage from 0.5 mg to 100 mg/kg, which corresponds to 0.5 - 100 ppm. However, the reference does not indicate HHC at 0.2-25 ppm would not prevent the growth of lactobacilli. Todd et al. shows HHC at high concentration (50-200 ppm) inhibits the growth of certain lactobacilli. Therefore, if the concentration of HHC is reduced to a lower concentration such as in the range of 0.2-25 ppm, the inhibition of the growth of lactobacilli would be lessened, which allows the growth of lactobacilli. Thus, the combined references result in the claimed invention and were, as a whole, prima facie obvious at the time the claimed invention was made. In response, applicants indicate Todd et al. only teach lactobacillus may be killed at a concentration above 50 ppm, the reference does not report any experiments conducted at concentrations below 50 ppm and provides no guidance as to whether and at what concentrations below 50 ppm HHC will stop inhibiting lactobacilli growth and prolifiration; and Table 1 (right column, pH 5.0) of the instant application indicates there is no growth of S. aureus when testing hexahydro beta acid at concentrations of 50, 100 or 0.2-25 ppm, thus, lowering the concentration does not automatically lessen the inhibitory action, which demonstrates the unpredictability of antibacterial action. Therefore, Todd et al. do not provide the conclusion that HHC concentration at 0.2-25 ppm lessened the inhibitory effect of HHC on lactobacilli (pages 7-9 of the response). The response has been fully considered, however, the argument is not found persuasive because of the following reasons: the data in Table 1 (right column, pH 5.0) are directed to S. aureus, which is different from lactobacilli indicated in Todd et al., and the data of Table 1 do not demonstrate the unpredicatbility of antibacterial action since some growth of S. aureus is indicated at concentrations 0.2-1.56 ppm and at pH 6.0 and 7.0 (left and middle columns), thus, lowering the concentration does lessen the inhibitory action; although Todd et al. do not indicate the inhibition level of lactobacilli growth at 0.2-25 ppm of HHC,it is obvious that the inhibition of lactobacilli growth would be lessened if the concentration of HHC is reduced by 250 fold (50/0.2); and Nutter et al. teach a method of killing bacteria such as S. aureus using the same amount of HHC, thus, it would be expected that HHC at concentration 0.2-25 ppm would inhibit the growth of S. aureus without preventing the growth of lactobacilli.

2. Claims 3-5, 12, 14, 15, 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutter et al. in view of Todd et al. as applied to claim 1 above, further in view of Lefren et al. (U. S. Patent 4,431,427). Nutter et al. teach a method of killing cancer cells or bacterial cells, and/or inhibiting their growth through the use of beta acids such as hexahydrocolupulone (HHC), and lupulones can be administered in a dosage from 0.5 mg to 100 mg/kg, which corresponds to 0.5 - 100 ppm. Todd et al. show HHC at high concentration (50-200 ppm) inhibits the growth of certain lactobacilli. The combined references teach HHC at a low concentration such as in the range of 0.2-25 ppm would inhibit the growth of S. Aureus without preventing the growth of lactobacilli. However, Nutter et al. and Todd et al. do not disclose the use of a product comprising an absorbent and HHC. Lefren et al. teach a tampon containing an organic acid in the absorbent material such as cotton fibers to create a hostile but safe environment during the use of tampon to inhibit the growth of pathogenic bacteria such as S. aureus. Thus, the combined references result in using a product such as tampon having HHC in the absorbent material at concentration of 0.2-25 ppm to inhibit S. aureus without preventing the growth of lactobacilli to maintain normal bacterial flora in a use environment such as vaginal area to avoid the onset of other bacterial infections. See the section above regarding the response to applicant's argument.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claim 16 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 103 (a) for claims 1-7, 12-21 and 23-25 .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
October 13, 2003